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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,566	10/16/2000	Zlatko Pflaum	2260/103	7125

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EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/600,566

Applicant(s)
Pflaum et al.

Examiner
Sandra Saucier

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 19, 2002
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-47 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Claims 24-47 are pending and are considered on the merits.

Specification

The drawings, Figures 1-4, which were part of the filing of PCT/IB99/00808 of which the instant application is a 371 National Stage application, have been entered into the case per the instructions of the PCT specialist Cecilia Tsang.

A new substitute specification should be submitted because of incorrect top margins which have resulted in punching through the text and loss of printed matter at the top of the pages in the specification.

Appropriate correction is required in order to expedite printing of the allowed claims.

Claim Rejections – 35 USC § 112

INDEFINITE

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 recites “the limited solubility”, but this term has no antecedent.

NEW MATTER

Claims 24-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Deletion of the term “limited-miscibility” from the phrase “limited-miscibility organic solvent”, broadens this phrase to include such solvents such as ethanol, methanol, acetone, etc. which are not included in the list of permissible solvents of this class on page 7, lines 26-37. Thus, the new limitation of “organic” solvent is clearly the insertion of a new concept and is, thus, new matter. Insertion of the list of solvents or the limits of miscibility would overcome this rejection.

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Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification.

Also, the insertion of the temperature limitation "wherein before crystallizing, the inhibitor is dissolved in said organic solvents at a temperature of between about 10 to 40C", does not have support in the specification. Applicants point to page 4, line 4 for support; however, in this place in the description the temperature limitation does not refer to dissolving the inhibitor in organic solvents, but rather in the fermentation broth, that is releasing it from the mycelium.

Applicants have inserted a limitation in the claimed method which is not in the method as disclosed and have thus, introduced a new concept. Introduction of new concepts is the introduction of new matter.

Claim Rejections – 35 USC § 102

Claims 40–42 and 46 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 4,319,039 [AB].

The claims are directed to a process for purifying HMG–CoA reductase inhibitors comprising crystallizing from a water-soluble organic solvent and from an organic solvent which has limited solubility in water.

The references are relied upon as explained below.

US 4,319,039 discloses a process for purification of HMG–CoA reductase inhibitors comprising crystallizing the ammonium salt of an HMG–CoA reductase inhibitor from a mixture of 50% chloroform, methanol, ammonium hydroxide (80:20:2)/ 50% ether and then recrystallizing from ethanol to yield greater than 99% purity. (col. 13, l. 22–45). The temperature of dissolving is not specified, thus it is assumed to be room temperature, since reference to heating or cooling (above or below room temperature) is found in the description of the method.

Response to Arguments

Applicants argue that the reference does not disclose purification of an inhibitor DIRECTLY from the fermentation broth using at least two

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crystallization steps at neutral pH using a water-miscible and a water-immiscible organic solvent.

This is true; however, please note that applicants claims are open to the insertion of other process steps. Closing the claimed method, that is using "consisting" to correspond to applicant's arguments might advance prosecution.

Applicants argue that the reference does not teach using both a miscible and immiscible solvent in two crystallizations. This is not true. Please see the reference where a mixture of chloroform/methanol/NH₄OH/ether (water immiscible mixture) is used to crystallize the inhibitor followed by crystallization from ethanol (col. 13, l. 22-45). Please note that applicants' claims allow for the insertion of other steps and thus applicants arguments do not correspond to the claimed method.

Conclusion

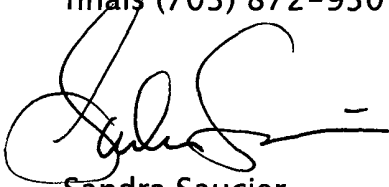
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 6:00 PM Monday and Tuesday and 8:30 AM-12:30 PM on Wednesday.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after hours (703) 872-9307.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish at the end.

Sandra Saucier
Primary Examiner
Art Unit 1651
April 17, 2002